510(k) Summary

SightSaverTM Visual Stimulator K113785

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					Contact Person
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Device Name	SightSaver TM Visual Stimulator				
Common/Usual Name	SightSaver TM				
Classification Names	21 CFR Classification Name Code				
/ Numbers and Code	882.1890 Evoked response photic stimulator GWE			GWE	
Regulatory Class	II				
Prescription Status	Prescription	n Device			
Device / Classification Panels	Diagnostic Neurological Devices				
	Cadwell LED Goggles		K8312	K831231	
Predicate Devices	XLTEK LED Visual Stimulator Goggles		K0117	K011794	
Technology	Embedded LEDs (Light-emitting diodes)				
Description of	The SightSaver TM Visual Stimulator is used to expose the eyes to				
Device	light in order to elicit a physiological response. LEDs inside the device flash light at the eye. The SightSaver TM Visual Stimulator is disposable and made with specifically shaped self-sticking adhesive foam padding which conforms to the periocular region of the patient's face.				
	The SightSaver TM is designed to be connected to a triggering and acquisition system which records, analyzes, or processes the patient's responses.				
	The triggering and acquisition system is not included as part of the 510(k).				

Predicate Comparison Summary				
Device Name	The SightSaver TM Visual Stimulator	Cadwell LED Goggles	XLTek Visual Stimulator Goggles K011794	
K Number	K113785	K831231		
Same Intended Use / Indications for Use	Yes	Yes*	Yes	
Utilizes embedded LED technology to flash visible light into the eyes for testing purposes	Yes	Yes	Yes	
Controlled by a separate triggering device	Yes	Yes	Yes	
Typical use flash repetition rate: 0.5Hz – 1.0Hz	Yes	Yes	Yes	
ISO 15004-2 compliant	Yes	No	No	

Conclusion

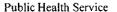
The SightSaverTM Visual Stimulator has been tested to higher safety performance standards compared with the predicate devices but is the same as the predicate devices in:

- Intended use
- Overall design and form factor
- Technological characteristics

The function and technology employed by the SightSaverTM Visual Stimulator is similar and introduces no new questions concerning safety and efficacy. Therefore, the SightSaverTM Visual Stimulator is substantially equivalent.

^{*}While Intended Use is the same, the specific wording of the Indications for Use was not available from the manufacturer of the Cadwell LED Goggles

DEPARTMENT OF HEALTH & HUMAN SERVICES





Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Anschel Technology Inc. c/o Dr. Glen Park Target Health Inc. 261 Madison Avenue, 24th Floor New York, NY 10016

JUN - 6 2012

Re: K113785

Trade/Device Name: SightSaver™ Visual Stimulator

Regulation Number: 21 CFR 882.1890

Regulation Name: Evoked response photic stimulator

Regulatory Class: Class II

Product Code: GWE Dated: June 1, 2012 Received: June 4, 2012

Dear Dr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113785
Device Name: SightSaver™ Visual Stimulator
Indications for Use:
The SightSaver™ is an evoked response photic stimulator that is used to apply a visible light stimulus to a patient's eyes for use in evoked response measurements or for electroencephalogram (EEG) activation.
The SightSaver TM Visual Stimulator is designed to be used in hospital and clinical settings by trained medical personnel and is for prescription use only.
Prescription UseX AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off) Page 1 of
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
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